PRESCRIPTION DRUG EVENT DATA

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Introduction

Background

In December 2003, Congress passed the Medicare Prescription Drug Benefit, Improvement and Modernization Act (MMA), allowing Medicare payment to MA organizations, PDP sponsors, and fallback plan sponsors offering coverage of outpatient prescription drugs under the new Medicare Part D benefit. For simplicity in this paper, we use the term "plans" to refer to these entities that contract with CMS to provide Part D benefits. The Act provided four summary mechanisms for paying plans:

1. direct subsidies
2. subsidized coverage for qualifying low-income individuals
3. federal reinsurance subsidies
4. risk corridor payments

Purpose of the document

The purpose of this document is to provide an overview of CMS's proposed approach to implement these four payment mechanisms. In order to make payment in accordance with these provisions, in our first Notice of Proposed Rulemaking (NPRM) of August 3, 2004 CMS proposed to collect a limited set of data elements for 100 percent of prescription drug claims or events from plans offering Part D coverage. We also requested public comment on the content, format, and frequency of data feeds. Based on further internal analysis, public comment on the NPRM, and informal industry consultation, we have further refined the set of data elements we anticipate collecting for Part D payment purposes. This document reflects our current thinking about which data elements we believe we will need (see Table 1), subject to final rulemaking. We still expect to collect 100 percent of events but only these limited data components per event.

We are distributing this draft for industry input and discussion. Our goal is to assure a common understanding of the data elements needed for payment, the role they would serve in the Part D payment process, and the necessity to collect them. This document is not a finalized request for required data, but rather represents CMS's understanding of what will be needed for making accurate, timely payment in accordance with the legislative provisions. We also remind readers that this document is based on the policies that were included in the NPRM. We are in the process of compiling the final rule and some of such policies may change in response to comments received. Therefore, this document cannot be viewed as a final document or announcing any CMS final policies. CMS final policies will be announced in the final rule. We expect industry comment and input, particularly from entities that anticipate offering Part D prescription drug plans. CMS expects to then complete the draft list by 2/1/2005 and after publication of the final rule.

We used four criteria in selecting the data elements:

1. Ability to pay plans timely and accurately using the four legislated payment mechanisms (direct subsidy, reinsurance, risk corridors, and low-income subsidy);
2. Minimal administrative burden on CMS, plans, and other entities including MA-PDs, PDPs, fallback plans, pharmacy benefit managers, pharmacies, and others;

3. Legislative authority; and
4. Validity and reliability of the data elements requested, such that the information would be useful.

Overview of contents
This paper focuses on how these data will be used for payment purposes. Much of the data, especially dollar fields, will be used primarily for payment. However, some of the data such as pharmacy and prescriber identifiers may be used for other legislated functions such as quality monitoring, program integrity, and oversight. In addition, we note that this paper only covers data collected on claims and does not cover data CMS may collect from plans through other mechanisms, for example collecting aggregate plan data for appeals processes.

The paper is a technical document that lays out how we propose that "claims" or prescription drug events be constructed for submission to CMS, what components would be mandated on events submitted to us for payment, and how the submitted data components fit together to allow calculation of payment under the four legislated mechanisms. Throughout the paper, we reference authorizing sections of the law.

In particular, Section I defines a prescription drug event (PDE) record. Many electronic transactions take place between plans, pharmacies, and intermediaries when an enrollee fills a prescription; this process allows determination of patient cost-sharing at the point of service and eventual adjudication where the plan pays the pharmacy. CMS proposes that plans submit a summary record of these intermediary transactions that would contain only information vital for CMS to know to calculate accurate payments.

Section II lists the proposed elements that would be required on PDE records submitted to CMS (also see Table 1) and discusses submission deadlines. We list brief definitions of each data element and how the claim field for the element would be populated. Section III lays out a subset of these data elements that together would enable CMS to identify a unique PDE record. CMS needs to be able to identify unique events in order to process adjustments and deletions for claims corrections.

Section IV deals with the issue of how plans would submit claims to CMS when claims originate from a beneficiary rather than the pharmacy. When beneficiaries submit paper claims to plans, they will not be able to submit on their claim all data elements listed in section II. Since the plan would then have incomplete data to pass on electronically to CMS for payment, CMS would waive the requirement for the full set of data elements and instead rely on a few selected elements. This section lists our proposed minimum required data set for this exceptional circumstance.

Section V defines drugs that are covered under the statute's Medicare Part D benefit and/or the Plan Benefit Package (PBP) versus those that are not. We propose modifiers for PDE records to enable us to distinguish covered and non-covered drugs. These flags would be vital for calculating costs that should be included or excluded from payment and/or true-out-of-pocket costs (TrOOP).

In section VI, we propose a process for handling adjustments that need to be made to previously submitted PDEs. Section VII discusses a mechanism to identify supplemental benefits on PDE records. Medicare does not pay for supplemental benefits (cost-sharing fill-in or coverage of non-Part D drugs) that extend beyond that standard or basic benefit defined in the MMA; these benefits must not be counted towards TrOOP, low-income subsidies, or reinsurance or risk corridor payments. Therefore, we have developed a schema for disaggregating the portions of claims or records that are attributable to supplemental coverage.

In section VIII, we define TrOOP and propose a process for segmenting out the portions of claims or records that must be counted towards TrOOP. We also describe a schema for identifying coverage by secondary or other payers so that this type of supplemental benefit is not counted towards TrOOP. Section IX explains the low-income cost-sharing subsidy (LICS) payment provision of the law. We define LICS and describe CMS proposals for advancing LICS payments to plans. We then lay out a methodology for tracking actual LICS expenditures on the PDE record as they are incurred so that paid and incurred amounts can be reconciled.

In section X, we discuss rebate accounting as it relates to claims. This section is not a comprehensive discussion of rebate cost accounting, rather we only address aspects that are intrinsic to reinsurance and risk corridor calculations derived from claims.
The MMA requires that CMS apply plan rebate dollars to the costs of Part D covered drugs and account for these rebate dollars in reinsurance and risk corridor calculations.
In this section we describe how PDE records data will be used to allocate rebate dollars for correct reinsurance and risk corridor payments.

Sections XI and XII are devoted to reinsurance and risk corridors. Previous sections describe data elements and calculations that would ultimately be used to conduct accurate reconciliation and calculate risk sharing dollars as detailed in sections XI and XII.
Section XI defines reinsurance and describes how we would derive reinsurance subsidy amounts from PDE data for reconciliation. Section XII is devoted to defining risk corridors and explaining how we propose to derive risk corridor payment amounts from PDE data.

Finally, note that Table 1 (draft data elements) and Table 2 (drug coverage status field) are located in the Appendix at the end of this document.

Draft Data Plan

I. Prescription Drug Event (PDE) Record

Most organizations or sponsoring entities will use a pharmacy benefit manager (PBM) or other third party administrator to process incoming claims from pharmacies. Claims typically undergo several rounds of transactions between these parties before the plan finally adjudicates a claim for payment. Plans and PBMs typically conduct final payment and reconciliation once every week or biweekly, and claims that are adjudicated during this period are referred to as "in-cycle" events.

CMS would require plans to submit only a summary record of a claim's status at the end of in-cycles given any adjustments that have occurred during that cycle. We define this summary record as a Prescription Drug Event (PDE) record and refer to it as such throughout this document. Table 1 lists our draft set of data elements for all PDEs (10 data elements from the NCPDP billing transaction, 7 data elements from the NCPDP billing response transaction, and 13 data elements defined by CMS for purposes of administering Part D, for a total of 30 data elements).

PDE records or "claims" would be submitted electronically by plans to CMS at least once a month. To the best of their ability, plans' summary records would reflect drug payment status at the end of in-cycles. However, this paper also proposes rules for submitting out-of-cycle claims and any hard copy claims plans may receive from beneficiaries.

Plans would have to submit PDE records, including adjustments, for events that take place during a given calendar year by the end of the third month of the following calendar year (CY) in order to receive payment. PDE records that are submitted to CMS after the third month of the subsequent calendar year would not be considered for payment and reconciliation. *For example, CMS expects that prescription drug claims including adjustments for all dates of service within CY 2006 will have to be submitted to CMS by March 31, 2007 in order to be processed for payment reconciliation.*

II. Data Elements

In Table 1, we list the draft data elements that plans would include when submitting PDEs to CMS for payment. We employed the National Council for Prescription Drug Programs (NCPDP) industry standard whenever possible. Most data elements represent existing NCPDP fields where we employ the same definition and field values that are currently in use per the NCPDP drug claim standard. CMS has also drafted several new fields for data that are not currently collected on industry drug claims but that would be necessary for us to pay plans in accordance with the new law. All fields are consistent with NCPDP formatting.

This section defines each data element and its specific potential use for CMS's payment process:

1. **Contract Number**
   This field contains the unique number CMS assigns to each contract that an entity has with CMS as an MA organization, a PDP sponsor, or a fallback entity. This data will be collected in the file header.

2. **Plan Benefit Package (PBP) ID**
   This field will contain the unique number CMS assigns to identify a specific PBP within a contract. CMS will utilize this data to ensure that each beneficiary's claims are being attributed to the appropriate PBP, i.e., the PBP in which the beneficiary is enrolled.

3. **Health Identification Claim Number (HIC#)**
   This field will contain the unique number that the Social Security Administration assigns to identify every Medicare beneficiary. For Railroad Retirement Board (RRB) beneficiaries, plans will use the RRB number. Plans must use other identifiers as member numbers (e.g., for plan membership cards), but all drug events submitted to CMS must use the HIC#. The HIC# ensures that CMS assigns drug event data to the appropriate beneficiary. The HIC# will also permit linkage of Part D drug event data to risk adjustment data, Parts A and B claims data, and eligibility and enrollment data.

4. **Patient Date of Birth (DOB)**
   Patient date of birth (DOB) shall be in CCYYMMDD format. DOB is used in conjunction with HIC# and gender to verify beneficiary identity and will be used as a cross check to ensure the event has identified the correct beneficiary.

5. **Patient Gender**
   Patient gender is reported as Male = 1, Female = 2, and Unknown = blank field. Together with HIC# and DOB, gender confirms the identity of the beneficiary.

6. **Date of Service (DOS)**
   Date of Service (DOS) is the date upon which the prescription was filled. This field should **not** contain the date on which the plan pays for the services or subsequent adjustments to the original event.

7. **Service Provider ID**
   This field identifies the pharmacy where the prescription was filled, populated with the pharmacy's NCPDP (formerly NABP) number. This data helps CMS identify a unique prescription drug event (see section III).

The following two fields pertain to identifying the prescriber. CMS requires use of a DEA number whenever it uniquely identifies the prescriber. In other cases, the prescriber's state license number should be used:

8. **Prescriber ID Qualifier**

This field indicates the type of identifier that is used in the Prescriber ID field. Consistent with NCPDP values for this field, it will be populated with 12 when DEA is used as the identifier type, or 08 when state license number is the identifier type.

9. **Prescriber ID**
  This field will contain the prescriber's unique identification number. It also helps identify a unique prescription drug event (see section III). As described above, CMS will require use of DEA number in this field or state license number when the DEA does not uniquely identify the prescriber. In addition, we note that if a universal or national provider identification number (NPI) is developed, CMS will consider transitioning to the new identifier for this field and will implement a transition schedule if we modify our transaction standard.

10. **Prescription/Service Reference Number**
  This field will contain the prescription reference number assigned by the pharmacy at the time the prescription is filled. It enables CMS to identify a unique prescription drug event (see section III).

11. **Product/Service ID**
  This field identifies the dispensed drug using a National Drug Code (NDC). In instances where a pharmacy formulates a compound containing multiple NDC drugs, the NDC of the most expensive drug shall be used.

12. **Compound Code**
This field will indicate whether or not the dispensed drug was compounded or mixed. The field will be populated with 1=Not compounded or 2=Compounded. This distinction will ensure that correct payments are made to the plan for mixed or compounded drugs. Plans may adjust the dispensing fee to include additional labor costs in the delivery of the compounded pharmaceutical item.

13. **DAW/Product Selection Code**
  This field will indicate the prescriber's instruction regarding substitution of generic equivalents or order to dispense the specific product written.

14. **Quantity Dispensed**
  This field indicates how many dosage units of the medication were dispensed in that the current fill (e.g., number of tablets, grams, milliliters, or other unit). This field is populated with up to three decimal places when the quantity is not a whole number.

15. **Days Supply**
  This field indicates the number of days' supply of medication dispensed by the pharmacy and will consist of the amount the pharmacy enters for the prescription. The supply should be between zero (00) and ninety (90).

16. **Fill Number**

This field indicates the number fill of the current dispensed supply, which must always be a value of zero (00) or greater.

17. Drug Coverage Status
   This field indicates whether or not the drug is covered under the Medicare Part D benefit and/or a specific PBP (see section V).

18. Adjustment/Deletion Flag
   This field distinguishes original from adjusted or deleted PDE records so that CMS's system can adjust claims and make accurate payment for revised PDEs. And "A" in this field flags a claim as a request for an adjustment, and a "D" flags a request for a deletion. On original claims, leave this field blank.
   An adjustment record must be submitted in order to request a change to an original or previously adjusted record (see section VI); a "D" record tells CMS to delete an original claim or an adjustment.

19. Beneficiary Submitted Flag
   This data will be used by CMS to flag PDEs that originate as beneficiary-submitted claims (see section IV). A "B" indicates a claim the plan received from a beneficiary, typically for reimbursement for services received outside of the plan service area, at an out-of-network pharmacy, or instances in which plan reimburses the beneficiary. Section IV details the circumstances under which CMS will accept claims that originate from beneficiaries and lists a reduced set of data elements that CMS will accept.

20. Out-of-Network (OON)
   This field will be populated with O when the claim is for an out-of-network service.

21. Catastrophic Coverage Flag
   This field indicates that a beneficiary has reached the out-of-pocket threshold or attachment point, at which point catastrophic coverage provisions should begin (reinsurance and reduced beneficiary cost-sharing - see section VIII). Populate this field with "A" on the claim when, according to plan records, a beneficiary has reached his/her attachment point. On all subsequent claims within a coverage year, populate this field with "C" to indicate catastrophic coverage.

The following three data elements represent the amounts we will be using from claims to determine costs that qualify for payment under the Medicare benefit:

22. Ingredient Cost Paid
   This field will contain the amount the plan paid the pharmacy for the drug itself. Dispensing fees or other costs are not included in this amount.

23. Dispensing Fee Paid
   This field will contain amounts paid to the pharmacy for dispensing the medication. Include only those activities related to the transfer of possession the drug from the

pharmacy to the beneficiary, including charges associated with mixing drugs, delivery, and overhead. The fee may be negotiated with pharmacies at the plan or PBM level.

24. Amount Attributed to Sales Tax

This field will contain any amount the plan paid the pharmacy to cover sales tax. No other costs are included in this field.

The following two fields must be reported on all PDE Records on which the attachment point is reached. The attachment point claim will normally have some costs above and some costs below the cap. These two fields will divide the Medicare qualifying costs into two components, indicating whether costs were incurred above or below the catastrophic cap. This delineation is required to comply with MMA Section 1860D-15(b) provisions to calculate reinsurance amounts based on actual incurred cost above the catastrophic cap:

25. Gross Drug Cost Below Catastrophic Cap

For the claim on which the attachment point is reached, this field represents the gross drug cost paid to the pharmacy below the catastrophic cap. This field is the amount of (Ingredient Cost Paid + Dispensing Fee Paid + Amount Attributable to Sales Tax) below the attachment point. (Note: the sum of 25 and 26 will be equivalent to the sum of Ingredient Cost Paid + Dispensing Fee Paid + Amount Attributable to Sales Tax).

26. Gross Drug Cost Above Catastrophic Cap

For the claim on which the attachment point is reached, this field represents the gross drug cost paid to the pharmacy above the catastrophic cap. This field is the amount of (Ingredient Cost Paid + Dispensing Fee Paid + Amount Attributable to Sales Tax) above the attachment point. (Note: the sum of 25 and 26 will be equivalent to the sum of Ingredient Cost Paid + Dispensing Fee Paid + Amount Attributable to Sales Tax).

27. Patient Pay Amount

This field lists the dollar amount the beneficiary paid (e.g., copayments, coinsurance, deductible, non-covered drug amounts, or other patient pay amounts). Amounts paid by State Pharmaceutical Assistance Program (SPAPs), charities, friends, family, or other qualified parties on behalf of beneficiaries will be reported in this field as a Patient Pay Amount. Plans are responsible for ensuring that beneficiaries are charged amounts that are consistent with their benefit packages as approved in the bidding process.

The following three data elements distinguish sources of subsidized payments that may be made on behalf of beneficiaries to reduce their cost-sharing liability. CMS will use these data to accurately calculate plan reinsurance and risk corridor payments:

28. Low Income Cost-sharing Subsidy Amount (LICS)

The MMA provides for Medicare payments to plans to subsidize the cost-sharing liability of qualifying low-income beneficiaries at the point of service (see section

IX). In accordance with statutory language, we refer to these amounts as Low-Income Cost-sharing Subsidies or LICS amounts. Cost-sharing amounts that would otherwise constitute beneficiary liabilities at the point of service will be paid by plans up front, when the pharmacy or PBM reconciles with the plan. The LICS claim field will contain plan-reported LICS amounts per drug event, so that CMS can reconcile prospective LICS payments made to plans with actual LICS costs incurred

29. Secondary/Other Payer Amount

Beneficiaries may have drug coverage from other payers in addition to any one participating Part D plan (see section VIII). If plans become aware of such coverage, they must report it to CMS and include amounts due from the supplemental payer(s) in this field. *Plans must also submit adjusted claims for all dates of service they determine should be covered by another payer.* CMS will use this data in calculating TrOOP (see section VIII) and conducting year-end reconciliation. *Note: This field should **not** include an SPAP as an additional payer.*

30. Supplemental Cost-share Amount

This field is the amount of cost-sharing that is subsidized (paid) by a plan under enhanced alternative coverage (see section VII). This plan payment amount is excluded from risk corridor payments. CMS may also use this data to assure that actual cost-sharing provisions are in accordance with the approved plan benefit structure from its bid.

III. Key fields to uniquely identify PDE record

Of the fields outlined above, we propose to use the following five fields to identify a single unique prescription drug event. We request industry input as to whether or not these fields are sufficient to identify unique PDEs. (A change in any of the following five fields would indicate a different event as opposed to an adjustment or deletion request for a previously submitted PDE):

    HIC#
    Service Provider
    Prescription/Service Reference Number
    Date of Service
    Fill Number

IV. Minimum data requirements for beneficiary submitted claims

Since the pharmaceutical industry is highly automated, CMS expects that Plans will almost always receive data electronically. However, there may be rare occasions when a Plan or PBM receives paper claims from a beneficiary. For example, a beneficiary might purchase an emergency prescription at an Out-Of-Network (OON) pharmacy and submit a receipt to the Plan for reimbursement. (Based on informal discussion with the industry, we expect the majority of beneficiary-submitted claims to be OON).

CMS realizes that beneficiary-submitted claims may not include all CMS-required data elements. Therefore, CMS would employ the following protocol in processing these claims. Plans would flag beneficiary-submitted claims by entering "B" in the Beneficiary Submitted Flag field, and we would suspend some edits and accept fewer data elements for claims with this flag:

> Gross Drug Cost Below Catastrophic Cap, Gross Drug Cost Above Catastrophic Cap - When Beneficiary Submitted Flag = B, CMS would waive reporting requirements for Ingredient Cost Paid, Dispensing Cost Paid, and Amount Attributed to Sales Tax. When a Plan did not have data to populate Ingredient Cost Paid, Dispensing Cost Paid and Amount Attributed to Sales Tax, CMS would accept Gross Drug Cost Below Catastrophic Cap and/or Gross Drug Cost Above Catastrophic Cap from the Plan and suspend routine processing to calculate these fields.

> Key fields - CMS would require all 5 key fields that uniquely identify a PDE except for Fill Number. If Fill Number were provided in the beneficiary-submitted source document, the Plan would be required to report it. However in its absence, CMS would accept a default value of 1.

CMS would oversee utilization of this minimum data set. We anticipate reviewing the volume of beneficiary-submitted PDEs as a percentage of total PDEs. If this percentage were higher than expected, we would research further and possibly reconsider use of minimum data requirements for beneficiary-submitted claims.

We would like comment from the industry about the feasibility of collecting minimum data requirements for beneficiary-submitted claims.

V. Drug Coverage Status

Under MMA section 1860D-2(e), CMS can pay only for drugs that both meet the definition of a "Part D drug" and are approved for coverage under a specific PBP. We refer to these medications as Covered Part D drugs under the following terminology:

> **Part D drug** – A Part D drug is any prescription drug not categorically excluded in 1927(k) of the Act (i.e., benzodiazepines, barbiturates, drugs used for anorexia, etc) or any prescription drug that is not covered under Part B).

> **Non-Part D drug** – any prescription drug categorically excluded in 1927(k) of the Act (i.e., benzodiazepines, barbiturates, drugs used for anorexia, etc) or drugs covered under Part B).

Covered Part D drug – A Covered Part D drug is a drug that meets the definition of a Part D drug and is also covered under a Plan. A covered Part D drug is a drug that is covered because:

(a) it is on the Plan's formulary or the beneficiary receives an exception or successfully appeals non-coverage;
(b) the drug is determined to be medically necessary by the Plan; and
(c) the drug is not otherwise excluded by the Plan for some reason listed in section 1862(a) of the Act (i.e., drugs used for cosmetic purposes, foot care, etc.).

Non-covered Part D drug - A non-covered Part D drug is a drug that meets the definition of a Part D drug but for some reason the Plan does not cover it – perhaps because it is off-formulary, perhaps because the Plan does not find it is not reasonable and necessary, or perhaps because the Plan believes the drug is excluded under 1862(a).

The MMA specifies that non-covered Part D drugs must be excluded from Reinsurance Subsidy (sec. 1860D-15(b)(2)) and Risk Corridor calculations (sec. 1860D-15(e)(1)(B)). No low-income cost-sharing subsidy (LICS) will be paid for non-covered Part D drugs (sections 1860D-14, 1860D-2). TrOOP must exclude any patient paid amounts for non-covered Part D drugs (sec. 1860D-2(b)(4)(C)(i)).

Section 1860D-2(e) defines what a "Part D drug" is. In some cases, CMS can determine whether a drug is a Part D drug from the data elements we propose to collect. For example, if a benzodiazepine is purchased by a beneficiary, CMS could identify the benzodiazepine NDC and ensure that no government payments are attributable to the purchase of that drug. In other cases, CMS cannot determine whether a drug meets the definition of a Part D drug because it depends upon the medical indication for which the drug is prescribed. Two examples illustrate situations when data elements are insufficient to determine whether a drug is a Part D drug.

- Example 1 – According to the law, a drug used for anorexia, weight loss or weight gain is not categorically excluded from Part D. Conceivably, a drug that is normally prescribed for anorexia may be used for another medically accepted indication. The Plan would need to determine if the drug is excluded from the definition of Part D drug based on whether or not it is used for an indication other than anorexia.
- Example 2 –The same brand of drug may be covered under Part B and under Part D. For example, a beneficiary will receive IV antibiotics through a drip infusion for 14 days at home. Staff from the home care agency will set up and monitor the IV. The beneficiary purchases the antibiotic at the retail pharmacy. Typically, IV antibiotics are administered in a physician office setting and are covered by Part B. Drugs that are covered under Part B are categorically excluded from the definition of Part D drug. Since the antibiotic will be administered

through drip infusion in the home setting, and is not covered under Part B, it meets the definition of a Part D drug.

Because covered Part D drug status has important ramifications, both CMS and the Plans must clearly understand how to categorize drugs. CMS proposes a new field, Drug Coverage Status, to document Covered Part D Status. The proposed Drug Coverage Status field will be populated with one of the following eight values. This value scheme incorporates 3 types of information: Part D/non-Part D drug status, Plan formulary status; and Plan approval/denial decision. This value scheme does not identify in detail the processes like step edits, prior authorization and appeal which the Plan might follow to reach the final approve/deny decision. (Table 2 summarizes the values and their implications for TrOOP, Reinsurance, and Risk Corridor calculations):

C1 – Part D drug, on Plan formulary, no approval required
C2 - Part D drug, on Plan formulary, approved
N1 - Part D drug, on Plan formulary, denied
C3 – Part D drug, not on Plan formulary, approved
N2 - Part D drug, not on Plan formulary, denied
X1 – Non-Part D drug, offered by enhanced alternative Plan as supplemental drug (may be reported by enhanced alternative Plan only)
X2 – Non-Part D drug, Plan paid for drug outside Part
X3– Non-Part D drug, denied

Example 1 – A beneficiary presents a prescription for a 30 day supply of hydrochlorothiazide 50 mg Tablet, 30 tablets. Hydrochlorothiazide 50 mg Tablet is on the Plan's formulary. The Plan requires no approval steps to dispense or pay. Drug Coverage Status = C1.

Example 2 – A beneficiary presents a prescription for a 30 day supply (30 capsules) for Sporonox 200 mg (itraconazole) Capsules. Itraconazole is on the Plan's formulary with prior authorization required. The beneficiary's physician prescribed itraconazole because the beneficiary has onychomycosis, confirmed by histological test (KOH, PAS stain) or culture. Treatment is limited to six months in duration. The clinical information provided by the physician met the authorization requirements. Drug Coverage Status = C2.

Example 3 – A beneficiary presents a prescription for a 30 day supply (30 tablets) of Effexor XR 150 mg (venaflaxine.) The Plan shows that no other antidepressants *have been prescribed previously,* including SSRIs or Tricyclics. The Plan's Pharmacy and Therapeutics Committee considers venaflaxine an agent that should be subject to step therapy and recommends that other agents be tried initially. The physician does not convince the Plan that the other anti-depressants that do not require step therapy would not be effective for the patient would have adverse effects or both. Drug Coverage Status = N1.

Example 4 – A beneficiary presents a prescription for a 30 supply (30 tablets) of Crestor 10 mg (rosuvastatin). Rosuvastatin is not on the Plan's formulary. The Plan covers Zocor (simvastatin) instead. Based on Plan policy for new enrollees, the Plan dispenses the prescription. The beneficiary is a new enrollee; he joined the Plan within the last week. Plan policy allows one fill of drug the patient is currently using until a visit with the beneficiary's selected physician. Drug Coverage Status = C3.

Example 5 – A beneficiary presents a prescription for a seven day supply (7 tablets) of Levoquin 750 mg (levofloxacin.) Levoquin is not on the Plan's formulary. The Plan covers Cipro 750 mg (ciprofloxin) tablets as the preferred agent and Cipro has not previously been tried in the treatment of the urinary tract infection. The physician does not convince the Plan that the other Cipro would not be as effective for the patient, would have adverse effects or both. Drug Coverage Status = N2.

Example 6 – A beneficiary presents a prescription for a ten day supply (10 tablets) of Dalmane 15 mg (flurazepam), a benzodiazepine agent. The beneficiary is enrolled to an enhanced alternative Plan that offers flurazepam on its Plan formulary as a supplemental drug. Medicare Part D does not cover benzodiazepines. However, this Plan offers it as a supplemental drug appropriate for short term use in healthy beneficiaries under the age of 75. Drug Coverage Status = X1.

Example 7 – A beneficiary presents a prescription for a thirty day supply (60 tablets) of Klonopin 0.5 mg (clonazepam), a benzodiazepine agent. Like all benzodizepines, Medicare does not cover Klonopin and Klonopin is not on the Plan's formulary. However the Plan decides to cover Klonopin at the Plan's own expense for this patient because it is appropriate for use as an anticonvulsant for this patient Drug Coverage Status = X2.

Example 8 – A beneficiary presents a prescription for Renova 0.05% Cream (tretinoin) from a dermatologist to reduce fine, facial wrinkles. The use of this product would be classified as cosmetic in nature. The Part D prescription drug benefit excludes coverage for drugs being used specifically for cosmetic purposes. The Plan should not cover this product. Coverage Status = X3.

VI. Adjustment/Deletion Process

CMS requires data elements and database functionality to process adjustments and deletions. CMS defines an adjustment or deletion as a change reported after the original PDE record was submitted. Adjustments and deletions can report data changes that are critical to Part D. For example, an adjustment can update delayed reporting of secondary health insurance payments that reduce TrOOP. We also expect deleted records when prescriptions are not picked up.

CMS will use the Adjustment/Deletion Flag to trigger adjustment/deletion processing. Adjustment/Deletion matching logic requires a seven-field match: the five key fields, Contract Number (reported in the header) and Plan Benefit Package. We added Contract Number/ Plan Benefit Package to reserve adjust/delete rights exclusively to the Contract Number/Plan Benefit Package that authored the original PDE record.

When CMS receives a PDE record with Adjustment/Deletion Flag = A (adjustment) or D (deletion), we will search the database for a preceding PDE record with matching values in Contract Number, Plan Benefit Package ID, HIC#, Service Provider, Prescription/Service Reference Number, Date of Service, Fill Number. When the preceding record is found, we will add "A" or "D" to the parent record. If the Adjustment/Deletion Flag = "A", we will establish a new active record with the new information. If the matching preceding record is not found, we will return an error message to the Plan.

CMS prefers that Plans submit PDE records at end-of-cycle. A PDE record, which may be an original, an adjustment or a deletion, will report the most recent information available during the cycle. Typically, cycle duration is one to two weeks. CMS will use the file submission date to identify the PDE. Because CMS uses submission date to identify the PDE, a single PDE can be submitted no more often than once per day.

VII. Fields for Supplemental Benefits
Note: Information in this section applies only to Enhanced Alternative Plans

Under the MMA sections 1860D-1 and 1860D-2, all Part D Plans are required to provide "standard" (sec. 1860D-2(b))or "basic alternative" (sec. 1860D-2(c)) prescription drug benefits.

However, Plans have the option to provide additional benefits that exceed the actuarially equivalent value of (i.e. are supplemental to) the standard or basic benefit (sec. 1860-D-2(a)(2). We refer to these Plans as "enhanced alternative" or supplemental[1] Plans. Supplemental benefits that enhanced alternative Plans offer can take two forms (sec. 1860D-2(a)(2)(A)(i-ii): 1) reduced cost-sharing (reduced coinsurance, copays, and/or deductibles and/or providing greater total dollar coverage amounts); and/or 2) coverage of non-Part D drugs. Per MMA sections 1860D-15(e)(4), Medicare does not pay for these supplemental benefits; rather, Plans fund them entirely from increased beneficiary premiums (sec. 1860D-13(a)(1)(C)).

The MMA does not allow supplemental benefits to be included in calculating the following amounts:

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[1] Part D uses the term "supplemental" to describe benefits that exceed standard coverage offered by enhanced alternative plans. Please distinguish between Part D use of the term "supplemental" from the generally accepted use of the term to describe additional health insurance that typically covers coinsurance amounts not paid by the primary health insurer. Secondary or other plans that fill in cost-sharing or provide other enhanced benefits are discussed in the Secondary/Other Payer section.

- Reinsurance subsidies (sec. 1860D-15(b)(2))
- Risk Corridor calculations (sec. 1860D-15(e)(1)(B))
- LICS will not be paid on supplemental drugs (sec. 1860D-14)
- Patient paid amounts for supplemental benefits are not included in TrOOP (sec. 1860D-2(b)(4)(C)(i)).

Data to identify supplemental benefits - To make correct payments, CMS requires data reported in 2 data fields to identify supplemental benefits:

1. Drug Coverage Status = X1 identifies supplemental drugs. This is a record level exclusion. PDE records with Drug Coverage Status = X1 will be excluded from Reinsurance, Risk Corridors, TrOOP and LICS.

2. Supplemental Cost-Share Amount – The data element Supplemental Cost-Share Amount reports the amount of cost-sharing that is subsidized (paid) by an enhanced alternative Plan. The dollar amount reported in Supplemental Cost-Sare Amount will be excluded from Risk Corridor calculations. The dollar amount reported in Supplemental Cost-Share Amount is mutually exclusive of any dollar amounts reported in Secondary/Other Payer Amount, LICS, and Patient Pay Amount.

CMS will use the following processing rules to exclude supplemental benefits as directed by the MMA:

- Reinsurance subsidy – Claims for supplemental drugs will be excluded from Reinsurance subsidy calculations (Drug Coverage Status = X1)
- Risk Corridor calculations –

    Claims for supplemental drugs will be excluded from Risk Corridor calculations (Drug Coverage Status = X1)

    The dollar amount reported in supplemental amount paid will be excluded from Risk Corridor calculations.

- LICS will not be paid on supplemental drugs (Drug Coverage Status = X1).
- TrOOP - Patient paid amounts for supplemental benefits (Drug Coverage Status = X1) are not included in TrOOP. Please note that only dollars in Patient Pay Amount and LICS fields in PDE records for covered Part D drugs are included in TrOOP. (PDE records with Drug Coverage Status = C1, C2, or C3 are considered covered Part D drugs).

VIII. True Out-of-Pocket (TrOOP) and Secondary/Other Payer

Definition: Our proposed rule defined True Out-of-Pocket (TrOOP) as allowable incurred costs that are payable by the beneficiary or by specified third parties on their behalf (namely qualifying SPAPs; family, friends, or others; and charities) within the limits of the standard benefit.[2]   Part D catastrophic benefits become effective when TrOOP reaches $3,600 (this value is specific to 2006 and increases annually each subsequent year as per sec. 1860D-2(b)(4)(B)(i)). When TrOOP reaches $3,600, we say the beneficiary has reached the "attachment point" or out-of-pocket threshold under the standard benefit.

For several reasons, both Plans and CMS need to track TrOOP costs as they accumulate or are incurred:
- TrOOP is pivotal to calculating Risk Corridors and Reinsurance.   Benefits that are provided by Plans after the beneficiary reaches the attachment point are eligible for Reinsurance subsidies and Reinsurance subsidies are then subsequently excluded from Adjusted Allowable Risk Corridor Costs.
- Tracking TrOOP is necessary so that beneficiaries are charged correct cost-sharing amounts at the point of service. When a beneficiary accumulates $3600 in TrOOP, the beneficiary enters the catastrophic phase of the benefit where they incur lower cost-sharing amounts (sec. 1860D-2(b)(4)).

Plans are primarily responsible for maintaining accurate accounting for TrOOP on a day-to-day basis. Plans are also responsible for reporting accurate beneficiary paid and LICS amounts on all events so that CMS can reconcile the TrOOP amounts.

CMS will use two fields on PDE records for covered Part D drugs to accumulate TrOOP: Patient Pay Amount and LICS. CMS will accumulate TrOOP amounts for each beneficiary from PDE records for each coverage year. As CMS receives PDE records, the system will increment the internal CMS accumulator with the Patient Pay Amount and the LICS documented in records whenever the Drug Coverage Status field is set to C1 or C2 or C3.

Because accurate TrOOP tracking is critical if Plans are to administer and pay the Part D benefit correctly, CMS will verify TrOOP tracking whenever beneficiaries reach the catastrophic cap. The proposed process would require Plans to identify attachment point status on PDE records using the field Catastrophic Covered Flag. Plans will assign Catastrophic Covered Flag = "A" (attachment point reached) on the PDE record that reaches the attachment point (TrOOP = $3,600.) To clarify, in one coverage year a beneficiary will have only one PDE record with Catastrophic Covered Flag = "A." Plans will assign Catastrophic Covered Flag = "C" (catastrophic coverage) on all successive claims to show that the beneficiary has reached the attachment point and is in the catastrophic phase of the benefit.

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[2] CMS defined qualified SPAPs in the proposed rule and is still developing rules regarding qualifying charities.

CMS plans to compare the internal TrOOP accumulator data to records with Plan reported data with Catastrophic Covered Flag = "A" or "C" to test the TrOOP accumulator algorithm and to test consistency between the Plan and CMS. CMS would compare CMS calculated TrOOP with Plan-reported Reinsurance in both directions. CMS would find beneficiaries whose TrOOP accumulator indicates that they have reached the catastrophic cap but for whom Plans are not reporting catastrophic coverage. CMS would also verify that beneficiaries for whom Plans are reporting catastrophic costs have reached the TrOOP attachment point for catastrophic coverage. We expect to find high agreement rates with most Plans.

Accurate TrOOP accumulation depends upon accurate reporting in the following fields: Patient Pay Amount, LICS, Secondary/Other Payer Amount and Supplemental Cost-Share Amount. The dollars reported in these fields are mutually exclusive.

> If a Plan mistakenly reported supplemental amount paid dollars or Secondary/Other Payer Amount dollars in the Patient Pay Amount field, TrOOP would be overstated.

> If a Plan mistakenly reported LICS dollars in the Patient Pay Amount field, TrOOP would be counted accurately, but the Plan would not receive payment to which it is entitled for paying the LICS. (For more information on LICS, see section IX).

Coordination of Benefits (Secondary/Other Payer Amount) – Under MMA, beneficiaries can still have multiple sources of drug coverage including current and former employers; SPAPs; military health coverage (Tricare); workers' compensation; spousal health care policies; and payments made by family, friends, or charitable organizations. However, as described above and in sec. 1860D-2(b)(4)(C)(ii), only payments made by beneficiaries or by selected third parties count or contribute towards TrOOP accumulation. Therefore, as stated above, payments from SPAPs will qualify for TrOOP and should not be reported as Secondary/Other Payer information. Conversely, payments due from other third parties such as wrap-around employer policies must be indicated as such in the Secondary/Other Payer Amount field so that they are not included in TrOOP. In the health care industry, this type of coverage is normally described as supplemental coverage. We have chosen not to use the term supplemental in this discussion because we do not want to introduce confusion with Part D terminology for supplemental benefits (also see section VII). Coordination of benefits information should always be reported as Secondary/Other Payer Amount.

If the original claim documents both Secondary/Other Payer Amount and Patient Pay Amount, CMS will interpret the Patient Pay Amount as TrOOP eligible. CMS will interpret the Secondary/Other Payer Amount as excluded from TrOOP. If an adjustment record shows a Secondary/Other Payer Amount and the original transaction did not show a Secondary/Other Payer Amount, CMS will assume that the Plan did not know about the additional health insurance when the original claim was processed. CMS will expect the Patient Pay Amount and Secondary/Other Payer Amount reported on the adjustment to

equal the Patient Pay Amount on the original record. In other words, the new Patient Pay Amount on the adjustment will exclude the Secondary/Other Payer Amount reported on the adjustment and only the new Patient Pay Amount will be counted towards TrOOP.

IX. Low Income Cost-sharing Subsidy (LICS)

Definition – MMA section 1860D-14 provides for Medicare payments to Plans to subsidize the cost-sharing liability of qualifying low-income beneficiaries, including Plan premiums, deductibles, coinsurances, and late enrollment penalties. The statute divides these income-related subsidies into two categories: premium assistance and cost-sharing assistance. The cost-sharing amounts that would otherwise constitute beneficiary liabilities at the point of service will be paid by Plans up front, when the pharmacy or PBM reconciles with the Plan. In accordance with statutory language, we refer to these amounts as Low-Income Cost-sharing Subsidies or LICS amounts. (CMS will make premium assistance and other LICS payments through non-claims related systems).

As described in the MMA Title I proposed rule, CMS plans to make monthly prospective payments to Plans to help cover LICS costs as they are incurred and will conduct final reconciliation at the end of the coverage year. As information systems evolve, CMS may instead reimburse Plans for LICS payments throughout the year as costs are incurred. Under either option, Plans must indicate LICS amounts paid on claims for CMS reimbursement or reconciliation. PDE data is the most efficient way to inform CMS that it owes the Plan money for this low income cost-sharing subsidy amount advanced to the beneficiary at the point of service.

Low income cost-sharing subsidy is unique to Medicare. Currently there is no NCPDP field to uniquely capture this information. In order to pay the Plan accurately, CMS will require a newly defined field, Low Income cost-sharing Subsidy (LICS). The following example shows how a Plan will populate the LICS field:

> An LICS-eleigible beneficiary receives a prescription with a $20 cost share. The beneficiary pays a $1 copay. The Patient Pay Amount field reports $1. The newly defined LICS field reports $19.

X. Rebates

Rebates are defined here as any price concessions that are provided after sale, as opposed to any price concessions that may have contributed to a lower negotiated ingredient cost at point of sale and that we would expect to be included in the price paid at the point of sale. Section 1860D-15(b)(2) of the MMA specifies that rebates are excluded from Reinsurance calculations, and section 1860D-15(e)(1)(b) specifies that rebates are excluded from Risk Corridor calculations.

In the proposed rule, we discussed the complexity of rebate accounting practices and reporting. We also requested suggestions for allocating and applying rebates, especially to Reinsurance. Based on our current estimates, we expect that Plans will report rebate information to CMS within six months of the end of the coverage year. Rebate dollars must be reported in full with no reduction for administrative cost or any other fees. The expected rebate information will consist of 3 data points: total rebate dollars, rebate dollars for non-covered Part D drugs, and rebate dollars for covered Part D drugs. The differentiation between non-covered Part D drug rebate dollars and covered Part D drug rebate is necessary so that Reinsurance and Risk Corridor calculations are based on covered Part D drug costs. This minimal data set will simplify Plan reporting while meeting the need for timely reconciliation including Reinsurance and Risk Corridor calculations.

The statute requires that we apportion covered Part D drug rebate dollars to Reinsurance and Risk Corridor calculations. We offer the following proposal for apportioning covered Part D drug rebate dollars to Reinsurance. We will identify all records for covered Part D drugs for the group of beneficiaries who reached the attachment point. We will identify the Allowable Reinsurance Costs (i.e. with Date Of Service on/after the attachment point). Then we will divide the post-attachment point Allowable Reinsurance costs by the total allowed costs (both pre and post attachment point). For example, a beneficiary in a basic Plan had $1,000 of Allowable Reinsurance Costs. The beneficiary had total allowed costs of $6100. The Reinsurance portion of the rebate for this beneficiary is calculated as $1,000 / $6,100 or 16.6.

The last step to determine the Reinsurance rebate savings is to multiply the covered Part D rebate dollars from the Plan by the Reinsurance rebate proportion (16.6%). The full amount of covered Part D rebate dollars is deducted from the Risk Corridor calculation.

XI. Reinsurance

MMA Section 1860D-15(b) describes Reinsurance. Reinsurance subsidies are designed to reduce the risk of participating in this new drug program. In general, CMS will subsidize 80 percent of covered Part D drug costs for beneficiaries in the catastrophic phase of the benefit. The enrollee enters the catastrophic phase of the benefit when she/he has accumulated $3,600 in TrOOP (for 2006).[3] We have also referred to this point as the attachment point (see section VIII). The Reinsurance subsidy applies to the majority of covered Part D drug costs incurred after the beneficiary reaches the attachment point (sec. 1860D-15(b)(2)). The statute gives directive to identify a small number of Reinsurance subsidy exclusions.

In addition to clarifying that the Reinsurance subsidy applies to drug costs accumulated after the beneficiary reaches the attachment point, the MMA discusses examples of three other Reinsurance subsidy exclusions based on Plan type, non-covered Part D drugs, and supplemental benefits. The term Allowable Reinsurance Cost applies to the costs from which the Reinsurance subsidy will be calculated (sec. 1860D-15(b)(2)).

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[3] The attachment point may increase in later years, based on the statute

Plan level exclusions - Section 1860D-15(e)(1)(B) of the MMA clarifies that fallback Plans do not receive Reinsurance, but are paid allowable costs under the standard benefit. Private fee-for-service Plans (PFFS) will receive Reinsurance, but the amount is not subject to the same year-end reconciliation that applies to MA-PD and PDPs.

Basic Coverage – Section 1860D-15(b)(2) explains that Allowable Reinsurance Costs are costs that would have been paid under the basic prescription drug coverage. We would exclude all costs related to drugs that the statute specifies as non-covered from our calculation of Allowable Reinsurance Costs. This includes classes of drugs that are non-covered in their entirety, any drugs used for a non-covered purpose, and drugs that are covered under Part D benefit but not covered under the approved Plan formulary or because of any other Plan rules. The Drug Coverage Status field will be utilized to identify those drug costs that do not qualify as Allowable Reinsurance Costs.

Gross Covered Drug Costs after the Attachment Point - To identify drug costs for beneficiaries who reached the attachment point, we will rely primarily on the Plan reported data. We will include drug costs reported in PDE records with a value of "C" reported in the Catastrophic Coverage Flag field and the dollars reported in the Gross Drug Cost Above Catastrophic Cap field on the single record which an "A" reported in the Catastrophic Coverage Flag field (see section II, #23). We will also compare records from output from the internal TrOOP accumulator.

CMS proposes a 6-step process to calculate the Reinsurance subsidy from PDE record data. This process first retrieves Reinsurance subsidy-eligible PDE records, then sums the appropriate fields on those records and finally determines 80% of the dollars reported in those appropriate fields:

1. Plan level exclusions - We will use Plan type assigned in HPMS to exclude drug data submitted by Fallback and PFFS Plans from Allowable Reinsurance Cost processing.

2. In order to limit Allowable Reinsurance Costs to basic prescription drug coverage we would use data in the Drug Coverage Status field. For example, we suggested that Plans report "X2" in the Drug Coverage Status field if the Plan decided to cover at its own expense a non-Part D drug like Klonopin (see section V). Part D would not cover Klonopin so, if it were dispensed after the beneficiary reached that attachment point, it would not be included in the PDE records from which we calculate the Reinsurance subsidy. We propose to exclude data reported as N1, N2, X1, X2, or X3.

3. To identify events with costs above the attachment point, we would sum (Ingredient Cost + Dispensing Fee + Amount Attributed to Sales Tax) reported on all PDE records with a value of "C" in the Catastrophic Coverage

Flag field plus the dollars reported in Gross Drug Cost Above Catastrophic Cap field on the single PDE record with a value of "A" reported in the Catastrophic Coverage Flag field.

4. At this point we have identified the dollars from which we would calculate the Reinsurance subsidy. We would multiply these dollars by the subsidy percentage of 80%.

5. We would sum the beneficiary totals calculated in step 4 to get the Plan total.

6. The last step in determining the Reinsurance subsidy is to subtract the Reinsurance portion of rebate. Section 1860D-15(b)(2) of the MMA states that Reinsurance subsidies exclude rebates. In the language of the statute, Allowable Reinsurance Costs include only costs that are "actually paid," and must be "net of discounts, chargebacks, and average percentage rebates." Section X explains the expected rebate information flow and calculations used to prorate the Reinsurance portion of the rebate.

Final Reinsurance Subsidy Reconciliation - After determining Plan-level Reinsurance subsidy, the final reconciled Reinsurance subsidy amount calculated above is compared to the total prospective Reinsurance subsidy payments the Plan received throughout the year. If the final reconciled Reinsurance subsidy amount is greater than the total prospective Reinsurance subsidy payments, CMS will pay the Plan the full amount of the difference (or increase payments in subsequent months). Conversely, if the final reconciled Reinsurance subsidy amount is less than the total prospectively Reinsurance subsidy payments, the Plan will repay CMS the full amount of the difference (or CMS may offset amounts against payments made in subsequent months).

XII. Risk Corridors

Background (MMA sec. 1860D-15(e)) - Application of Risk Corridors is designed to limit exposure to unexpected expenses not already included in the Reinsurance subsidy or taken into account through health status risk adjustment. CMS and the Plan share a portion of the profits or losses resulting from expenses for basic benefits. Risk Corridor calculations compare the Plan's Adjusted Allowable Risk Corridor Costs to the Plan's target amount. If Adjusted Allowable Risk Corridor Costs exceed the prepayments by a certain amount, the Plan is reimbursed a percentage of the difference to help Plans with a portion of the unanticipated expenses associated with their drug coverage. On the other hand, if prepayments exceed Adjusted Allowable Risk Corridor Costs, Plans pay the government back a percentage of the difference.

Target amount (sec. 1860D-15(e)(3)(B)) – The first step in determining a Risk Corridor is to establish a Plan's target amount. The target amount is based on actual direct subsidy payments and premiums paid to the Plan during the course of the year. The subsidy payment amount for each beneficiary is obtained by taking the risk adjusted bid and

subtracting the beneficiary premium. The payment system will be calculating these amounts every month in order to make the monthly capitated payment. When we calculate Risk Corridors, we will obtain from the payment system the total amount of premium and direct subsidy payments for the coverage year. Since administrative costs are excluded from the target amount, we would reduce the total of direct subsidy payments and premiums by an administrative cost percentage that the Plan submits with the bid.

Therefore, the target amount is calculated as follows:

Target amount = (1.00 – administration cost percentage) * (total direct subsidy + total beneficiary premium),

where the direct subsidy = standardized bid * beneficiary risk adjustment factor – beneficiary premium,

the total direct subsidy is the sum of all monthly beneficiary direct subsidy amounts paid for the entire coverage year, and the total beneficiary premium.

Adjusted Allowable Risk Corridor Costs - In accordance with MMA section 1860D-15(e)(1), there is a 5-step process to identify Adjusted Allowable Risk Corridor Costs

1. Exclude claims for non-covered Part D drugs. Drug Coverage Status values N1, N2, X1, X2, and X3 identify non-covered Part D drugs (see section V).

2. Calculate Allowable Risk Corridor Costs for the basic benefit, using the following fields:

   Gross Covered Drug Cost [4]
   - Patient Pay Amount
   - Low Income cost-sharing Subsidy
   - Secondary/Other Payer Amount
   - Supplemental Cost-Share Amount

   Gross Plan-Paid Covered Drug Cost

3. Exclude induced utilization (applies only to enhanced alternative Plans) Multiply result of formula above by (1.00 – induced utilization percentage).
4. Subtract Plan Level Reinsurance subsidy (see section XI).
5. Subtract Part D covered rebate dollars (see section X).

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[4] The sum of (Ingredient Cost + Dispensing Fee + Amount Attributed to Sales Tax)

Calculate the Plan's Risk Corridors **-** Risk Corridors are calculated based on the target amount plus or minus the threshold risk percentages associated with each Risk Corridor limit. For instance, in 2006 the first Risk Corridor is defined as 2.5 percent above the target amount and the second as 5 percent above the target amount. If a Plan's target amount is $1m, the first upper limit is $1,025,000 (target + .025 * target amount or $1,000,000 + $25,000.) The chart below shows the Risk Corridor thresholds for a Plan with a $1,000,000 target amount.

In 2006 and 2007:	1st Threshold	2nd Threshold
Threshold risk percentage (MMA-Section 1860D-15(e)(3)(C)	2.5%	5.0%
Upper Threshold limit (target + Target * threshold risk percentage)	$1m + ($1m * .025) = $1,025,000	$1m + ($1m * .05) = $1,050,000
Lower Threshold limit (target – Target * threshold risk percentage)	$1m – ($1m * .025) = $975,000	$1m – ($1m * .05) = $950,000

Calculation of Payment Adjustment – Payment adjustment is based on comparison of the Plan's Adjusted Allowable Risk Corridor Costs to Plan-specific Risk Corridor thresholds.

> There is no payment adjustment if the Plan's Adjusted Allowable Risk Corridor Costs fall within the first Risk Corridor.

>> For example, if the target amount is $1m, and if the Adjusted Allowable Risk Corridor Costs are at least equal to the first threshold lower limit ($975,000) of the Risk Corridor but not greater than the first threshold upper limit ($1,025,000) of the Risk Corridor, there is no payment.

> There is a payment increase if Adjusted Allowable Risk Corridor Costs are above the upper limit of the first or second Risk Corridor.

>> For Adjusted Allowable Risk Corridor Costs between the first threshold upper limit and the second threshold upper limit, the Plan is paid 75%[*] of the difference between Adjusted Allowable Risk Corridor Costs and the first threshold upper limit.

>>> For example, if the target amount is $1m, and if the Plan's Adjusted Allowable Risk Corridor Costs = $1,030,000, the Plan is paid $3,750(.75 * ($1,030,000 - $1,025,000))

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[*] In 2006, the 75% rate will change to 90% for the first and second upper thresholds if certain circumstances are met (MMA sec. 1860D-15(e)(2)(B)(iii)).

For Adjusted Allowable Risk Corridor Costs above the second threshold upper limit, the Plan is paid the sum of 75%* of the difference between the second threshold upper limit and the first threshold upper limit and 80% of the difference between the Plan's Adjusted Allowable Risk Corridor Costs and the second threshold upper limit.

> For example, if the target amount is $1m, and if the Plan's Adjusted Allowable Risk Corridor Costs = $1,052,000, the Plan will be paid $20,350 (.75 * ($1,050,000 - $1,025,000) + .8 * ($1,052,000 - $1,050,000))

There is a payment reduction if Adjusted Allowable Risk Corridor Costs are below the lower limit of the first Risk Corridor.

> If the Plan's Adjusted Allowable Risk Corridor Costs are between the 1st and 2nd threshold lower limit, the payment reduction equals 50% of the difference between first threshold lower limit of the Risk Corridor and the Plan's Adjusted Allowable Risk Corridor Costs.
>
>> For example, if the target amount is $1m, and if the Plan's Adjusted Allowable Risk Corridor Costs = $973,000, the Plan repays $1,000 (.5 * ($975,000 - $973,000)
>
> If the Plan's Adjusted Allowable Risk Corridor Costs fall below the second threshold lower limit, the payment reduction equals the sum of 50% of the difference between the 1st and 2nd threshold lower limit and 80% of the difference between the Plan's Adjusted Allowable Risk Corridor Costs and the 2nd threshold lower limit.
>
>> For example, if the target amount is $1m, and if the Plan's Adjusted Allowable Risk Corridor Costs = $949,000, the Plan repays $13,300 (.5 * ($975,000 - $950,000) + .8 ($950,000 – $949,000).

Appendix

Table 1 – Prescription Drug Event Record Data Elements

Table 2 – Drug Coverage Status Field Values